

PROGRAMMABLE INJECTOR CONTROL**CROSS-REFERENCE TO RELATED APPLICATION**

5

This application is a continuation of copending Application Serial No. 09/365,278, filed on July 30, 1999, the contents of which are hereby incorporated by reference.

10

FIELD OF THE INVENTION

The present invention generally relates to powered injectors and syringes for use therewith, and more particularly, to methods and apparatus for automatically controlling the same.

15

BACKGROUND OF THE INVENTION

20

25

30

A number of injector-actuated syringes and powered injectors for use in medical procedures such as angiography, computed tomography, ultrasound and NMR/MRI have been developed. U.S. Patent No. 4,006,736, for example, discloses an injector and syringe for injecting fluid into the vascular system of a human being or an animal. Typically, such injectors comprise drive members such as pistons that connect to a syringe plunger. For example, U.S. Patent No. 4,677,980, discloses an angiographic injector and syringe wherein the drive member of the injector can be connected to, or disconnected from, the syringe plunger at any point along the travel path of the plunger via a releasable mechanism. A front-loading syringe and injector system is also disclosed in U.S. Patent No. 5,383,858.

U.S. Patent No. 5,494,036 discloses a patient infusion system adapted for use in MRI. The infusion system is designed to be substantially non-reactive with the magnetic field generated by the magnetic resonance imaging system for producing diagnostic images.

Medrad has also developed a control arrangement ("SPECTRIS") for an MRI infusion system that uses two syringes, namely, one for the introduction of contrast medium into a patient and the other for a flushing medium. As is known conventionally, it is often desirable to flush from the tubing of an infusion system a residual quantity of contrast medium that remains there after a given infusion procedure, as contrast medium tends to be expensive and its efficient use, without waste, is often seen as a top priority. The "SPECTRIS" control arrangement will thus not only account for the residual contrast medium left in the tubing, and aim to use it in an infusion procedure, but will utilize a much cheaper flushing medium, such as a saline solution, in order to serve the purpose of pushing the residual contrast medium through the tubing and even through the patient's body (so as to "push" and deliver contrast medium to a region of interest in the body). Other advantageous purposes have also been recognized in connection with such flushing media, such as maintaining a flow through the patient's veins for a predetermined period of time in order that the veins will be better prepared to subsequently receive a new infusion of contrast medium.

The "SPECTRIS" control arrangement is a pre-programmable arrangement for establishing a precise protocol for the infusion of contrast medium followed by

flushing medium. At the time that the "SPECTRIS" system was established, needs in the industry were generally such that only some very simple protocols were desired. Thus, the "SPECTRIS" system addressed such needs by
5 permitting protocols in which one or two "phases" of contrast medium took place followed by zero, one or two "phases" of flushing medium infusion. "Phase" refers to the application of a given quantity of a given medium at, for example, a fixed flowrate for a fixed period of time.
10 Thus, up to two phases each of contrast medium and flushing medium, for example, were permitted by the "SPECTRIS" system, in order to provide a patient with different modes of infusion one after the other to serve particular purposes.

15 Of late, however, some disadvantages have been noted in connection with the "SPECTRIS" control system and other related systems. Not the least of these is the lack of flexibility in developing and administering infusion protocols to a patient, as the "SPECTRIS" system
20 would allow no more than two distinct phases for each medium, and no single phase of flushing medium infusion could take place between two different phases of contrast medium infusion.

25 A further disadvantage has been recognized in that the aforementioned phases will typically be administered one after the other without the opportunity for an intermediate pause or hold between phases. This would appear to limit the convenience and utility of the system in question in many respects.

30 Nemoto and Co., Ltd., of Tokyo, Japan has also developed a control system for an MR injector. However,

this appears to be even less flexible than the "SPECTRIS" system in that only protocols consisting of no more than one contrast medium infusion and no more than one flushing medium infusion appear to be permitted.

5 In the realm of CT (computed tomography)
injection technology, Medrad has developed the "ENVISION"
control system. As flushing media have generally not
been hitherto employed in CT injector systems, the
"ENVISION" system, much as any conventional CT injector
10 control system, contemplates only the use of a single
syringe for patient infusion, and solely for use with
contrast medium. The "ENVISION" system permits protocols
that employ up to eight different phases of contrast
medium infusion, wherein each phase may employ a
15 different infusion flowrate, infusion quantity and/or
infusion duration. Pre-programmed pauses between
infusion phases are also conceivable within such a
context.

20 Evolving needs have thus been recognized in
connection with providing an injection control system
that is much more readily adaptable to a wider range of
contexts.

SUMMARY OF THE INVENTION

25 Generally, at least one presently preferred
embodiment of the present invention broadly contemplates
a fluid injection arrangement, in the context of patient
imaging systems, in which phases of contrast medium
injection and flushing medium injection can be freely and
selectably ordered so as to make available to the

operator and patient a vast array of possible protocols that has hitherto been essentially unattainable.

5 The present invention also broadly contemplates the use of a "hold" phase, involving an indefinite pause between phases of a protocol, in connection with such imaging systems.

10 Also broadly contemplated herein is the use of a "pause" phase in which a pause of fixed duration is pre-programmed into the protocols of MRI injector systems.

BRIEF DESCRIPTION OF THE DRAWINGS

15 The present invention and its presently preferred embodiments will be better understood by way of reference to the detailed disclosure herebelow and to the accompanying drawings, wherein:

Figure 1 is a schematic depiction of a conventional magnetic resonance imaging (MRI) injector system arrangement;

20 Figure 2 is a pictographic depiction of a conventional MRI injector system arrangement; and

Figures 3-6 are various depictions of a control screen arrangement for use with different protocols.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

25 Figures 1 and 2 generally illustrate a conventional MRI injector system arrangement, such as is

disclosed in U.S. Patent No. 5,494,036 to Uber et al, the contents of which are incorporated herein by reference. A magnetic resonance injector system is shown generally at 10. The MRI system includes a system controller 12 which incorporates a computer 14 and a battery charging unit 16. The system controller 12 is located externally of the imaging room 17, the imaging room being shielded from electromagnetic interference by a shield 18.

Isolation can be achieved by completely enclosing the room with copper sheet material or some other suitable, conductive layer such as wire mesh. Communication line 20, connects the system controller 12 with an external infrared/optical communications transceiver 22. The shielded imaging room 17 also incorporates a patient viewing window 24 in the shield 18 which allows an operator to view the imaging room. The window 24 can be formed by sandwiching a wire mesh material (not shown) between sheets of glass or coating the window with a thin coating of conductive material such as gold (not shown) to maintain the continuity of the electromagnetic shield 18.

An infrared/optical communications transceiver 26 is positioned internally of the imaging room 17 at the viewing window 24 opposite the external communications transceiver 22 such that the internal and external communications transceivers communicate with each other through the viewing window with no breach of the electromagnetic shield. A communications link 28 located within the shielded area connects the internal infrared/optical transceiver with an injection control unit 30. The injection control unit 30 is powered advantageously by rechargeable battery 32. The injection

control unit 30 also incorporates control circuitry which controls electric motors 35, 36 which are also located within the injection control unit. The injection control unit is contained within an electromagnetic shield 37 to prevent interference with the magnetic field used to generate the magnetic resonance image.

The injection head unit should preferably be located in close proximity to the patient in order to decrease the distance that the contrast media fluid must travel from the contrast media injectors. The injection head unit 38 includes contrast media injection syringe and piston units 40, 42. The syringes 40, 42 are in operation communication with the electric motors in the injection control unit by flexible mechanical drive shafts 44, 46, respectively. The drive shafts are preferably made from a nonferrous metal such as hard brass.

The disclosure now turns to an embodiment of the present invention, as illustrated in Figures 3-6, that could conceivably be employed in connection with a MRI injector system such as that shown in Figures 1 and 2 or with any other of a wide range of MR, CT, angiographic or ultrasound injector systems. These possible uses of at least one embodiment of the present invention are elucidated in greater detail herebelow.

Shown schematically in Figures 3-6 are various incarnations of a touch screen arrangement 200 that could be employed in accordance with at least one presently preferred embodiment of the present invention. As a non-restrictive example, such a touch screen arrangement could be utilized in conjunction with a system controller

12 and computer 14 such as that described and illustrated hereinabove with respect to Figures 1 and 2. While a touch screen arrangement is contemplated in connection with Figures 3-6, it is to be understood that other types of data entry arrangements are conceivable that would achieve an equivalent purpose. Display fields 210, 220 could also be touch fields used for desired purpose. For example, soft or hard key entry could be used, as well as trackball arrangements, mouse arrangements, or a cursor control touch pad (remote from the screen).

As shown in Figure 3, touch screen arrangement 200 may permit for the display of a display field 210 corresponding to the available quantity of contrast medium, a variable column 212 of touch fields for facilitating the entry of control parameters relating to contrast medium, a variable column 214 of touch fields relating to flowrate, a variable column 216 of touch fields relating to volume, a variable column 218 of touch fields for facilitating the entry of control parameters relating to flushing medium and a display field 220 corresponding to the available quantity of flushing medium. Display fields 210, 220 could also be touch fields used for a desired purpose.

The term "contrast medium", as employed herein, refers to essentially any suitable type of medium, as used in the medical arts, that is injected into a patient and, in the context of an imaging process (such as MR, angiography, ultrasound or CT), facilitates in highlighting selected areas of the patient's body while he/she is being scanned. In addition, the term "contrast medium", as employed herein, also refers to other diagnostic or therapeutic agents for injection into

patients. The term "flushing medium", as employed herein, refers to essentially any suitable type of medium, such as a saline solution, that can be used to flush contrast medium from the tubing of an infusion system and that is well-suited for flowing through the patient's body so as to serve a useful supplementary purpose, such as keeping his/her veins open in preparation for another infusion of contrast medium.

As will be appreciated throughout this disclosure, the touch screen arrangement 200 is preferably configured for permitting the operator to freely and flexibly incorporate phases of contrast medium infusion and phases of flushing medium infusion with respect to one another in a manner that has hitherto apparently not been contemplated nor realized. (A definition of "phases" may be found in the "Background" section of this disclosure). Further, the present invention also broadly contemplates, in accordance with at least one presently preferred embodiment, optional "hold" and "pause" phases as discussed herebelow.

Accordingly, Figure 3 illustrates one conceivable protocol that may be entered in accordance with an embodiment of the present invention. As shown, displays 210 and 220 show that 50 ml of contrast medium are available, as are 83 ml of flushing medium. Also, the operator has selected the provision of two phases of contrast medium followed by one phase of flushing medium.

Preferably, the first phase of contrast medium infusion will have been set by activating the touch field 1 in column 212, followed by activating the corresponding entry fields in columns 214 and 216 and entering in them,

respectively, the desired flowrate and desired volume to be administered to the patient. The entry of data can be accomplished by touching on a touch field (214 or 216), which could prompt the appearance of a key pad on the screen that would allow the entry of specific values in the fields 214, 216.

As shown, a second phase of contrast medium infusion has also been set in similar manner, but this time by activating touch field 2 in column 212, followed by activating the corresponding entry fields in columns 214 and 216 and again entering in them, respectively, the desired flowrate and volume.

For the third phase, as shown in Figure 3, the operator has selected a flushing medium infusion phase, this time by activating touch field 3 in column 218 and then entering the desired flow rate and volume parameters in the corresponding fields in columns 214 and 216.

The result is a three-phase protocol that will result in the administration of: (1) a first phase of contrast medium infusion (10 ml) at 2.0 ml/s; (2) a second phase of contrast medium infusion (20 ml) at 1.0 ml/s; and (3) a phase of flushing medium infusion (25 ml) at 1.0 ml/s. Such a protocol might be desirable, for example, when it is desired that a patient first receive a first, quick infusion of contrast medium of smaller volume (i.e., a bolus of contrast medium) so as to accentuate (for imaging purposes) a small, particularized part of the body where such an infusion may be desirable (e.g., the kidneys), followed by a second, slower infusion of contrast medium of larger volume (e.g., a trickle or drip of contrast medium) that would be of use

in a larger part of the body where a faster flowrate might not be needed (e.g., peripheral vascular regions of the legs). The flushing phase, then, could subsequently be utilized for purposes such as those described heretofore.

In a preferred embodiment of the present invention, touch screen arrangement 200 may be so configured as to display only those data entry fields in columns 214, 216 that have been specifically activated by the operator (via activation of corresponding touch fields in columns 212, 218), so that there will be no data fields visible in columns 214, 216 corresponding to phases that are not to be used for a given protocol. Thus, Figure 3 shows that no data fields are visible in columns 214, 216 in correspondence with a fourth phase, since only three phases are being employed. Further, there will only preferably be one touch field in columns 212 and 218 visible beyond the number of phases that has already been chosen by the operator. Thus, as shown in Figure 3, three phases have been entered and the touch fields 4 in columns 212 and 218 are visible in preparation for possible activation of a fourth phase by the operator. In the meantime, a suitable icon 222 (preferably having use in connection with a "hold" phase, as described later) may be provided in place of the absent data entry fields in columns 214 and 216. Accordingly, it will also preferably be the case that, prior to the activation of any phases at all, at an introductory stage of the process, no touch fields in columns 212-218 will be visible at all except for the touch fields 1 in the first row.

As shown, the incrementally emerging data fields in columns 214 and 216 may assume different shades, in correspondence with the type of phase being employed. Thus, in the embodiment illustrated in Figure 3 (as well as Figures 4-6), the data entry fields assume a darker shade in correspondence with a contrast medium infusion phase, while they assume a lighter shade in correspondence with a flushing medium infusion phase. Further, the numbered touch fields in columns 212 and 218 may each preferably assume a corresponding shade in accordance with their being individually activated. Thus, fields 1 and 2 in column 212 are shaded in correspondence with their having been activated in the process of setting up two contrast medium infusion phases (following from their proximity to display field 210, which corresponds to contrast medium), while field 3 in column 218 is shaded in correspondence with its having been activated in the process of setting up a flushing medium infusion phase. In contrast, neither of the fields 4 in columns 212, 218 are shaded since neither has been activated to set up a phase of any sort.

The concept of incrementally emerging data fields in columns 214, 216, as discussed above, helps illustrate the flexibility and versatility afforded in accordance with at least one presently preferred embodiment of the present invention. Particularly, in the embodiment illustrated in Figure 3, data fields emerge only to the extent that they are needed and can apply to either a contrast medium infusion phase or a flushing medium infusion phase at the behest of the operator. Such an arrangement would appear to stand in stark contrast to those conventional arrangements, such as the "SPECTRIS" arrangement described heretofore, in

which the order of phases is comparatively fixed and inflexible.

Also illustrated in Figure 3, *inter alia*, are a duration display field 224 and a total volume display field 226. These preferably will serve as, respectively, a clock of elapsed time that starts from zero and spans the duration of the totality of the phases that have been entered and an indicator of the total volume of fluid (destined for the patient) that has been expended over the totality of the phases. As shown in Figure 3, duration display field 24 also preferably shows the projected total duration before injection starts, and volume display field 226 also preferably shows, at that time, the total projected volume to be expended.

Figures 4-6 serve to further illustrate the versatility and flexibility afforded in accordance with at least one presently preferred embodiment of the present invention. Reference numerals in those figures relate to similar components referenced by similar numerals in Figure 3.

In the protocol shown in Figure 4, the operator has chosen a first phase of contrast medium infusion, followed by a first phase of flushing medium infusion, followed by a second phase of contrast medium infusion, finally followed by a second phase of flushing medium infusion.

Figure 5 illustrates a different protocol, but this time involving six phases. Particularly, the six phases illustrated are two separate contrast medium phases, followed by a flushing medium phase, followed

again by two distinct contrast medium phases, finally followed by a flushing medium phase.

Finally, Figure 6 illustrates a protocol involving a distinct "hold" phase in accordance with an embodiment of the present invention. As shown here, the operator has selected a contrast medium phase followed by a flushing medium phase. However, the operator has also now selected a "hold" phase, indicated at 244, in which, for an indefinite period of time (possibly capped automatically for safety reasons), the regulated administration of fluids may cease. The "hold" phase may be activated on touch screen arrangement 200 by pressing on icon 222, which would then produce a "hold" display field 244 that spans both columns 214, 216. The "hold" phase is then followed by a second contrast medium phase and a second flushing medium phase.

The value of including a "hold" phase is that it permits some time for the operator to render supplementary judgements, following the administration of the phase(s) before the "hold", that could be of value when administering the phase(s) that occur(s) after the "hold". As an example, and as can be appreciated from the protocol shown in Figure 6, the operator may wish to first infuse a short bolus of contrast medium not for imaging purposes but for the purpose of determining the length of time (by any suitable means) that the bolus requires in order to reach a given target area in the patient's body. Once a flushing phase is completed, the "hold" may then take effect. During the "hold", the imaging scanner (not shown here) could be programmed to delay its imaging action for a period of time that corresponds to the "delay" that the "short bolus"

required in order to reach the target area of the body. In turn, the scan delay (i.e., the length of time that the scanner could "wait" before imaging the target area of the body) can be entered into a display field 228 by means of a touch field 228a suited for that purpose. In this manner, when the time comes to administer the second contrast medium phase, the resulting bolus will be permitted to pass through the patient's system for a length of time corresponding to the "scan delay" before the scanner, conceivably prompted automatically via the scan delay clock in field 228 or perhaps manually by the operator (for example, upon hearing an audible signal), itself is activated as to image the target area of the patient. In this manner, the scanner will be active for only such a length of time as is clearly necessary for imaging the target area, thus providing a highly desirable cost savings.

Other touch fields and display fields may be provided within touch screen arrangement 200. As shown in Figures 3-6, a KVO ("keep vein open") display field 230 may show the status of "KVO", that is, whether there is a circulation of flushing medium (either continuously or in small intermittent bursts) in the patient's system for the purpose of maintaining a flow of some type in his/her veins and perhaps to show a countdown of the time remaining in such a state. The duration of "KVO" could preferably be capped, in correspondence with the actual quantity of flushing medium available (minus the flushing medium required for any subsequent flushing medium phase), automatically by the control system. Thus, automatic shutoff could take place when the reservoir of available flushing medium has decreased to a point at which, with further depletion, there would not be a

5 sufficient amount of flushing medium for a subsequent
flushing medium phase or phases. It will be appreciated
that "KVO" is not so much a flushing phase *per se* but
instead is a "maintenance" phase in which the patient's
veins are maintained in a relatively open state in
preparation for the subsequent administration of contrast
medium, or possibly even for other reasons. "KVO" could
thus well take place during a "hold" phase so that, for
example, the patient's veins could remain relatively open
and free while the aforementioned intermediate
calculations, etc., are taking place. Normally, the
rate, volume and frequency of delivery in "KVO" is fixed
ahead of time but it could also be variably programmed by
the operator, by any suitable means.

15 The "arm injector" display field 232 and
associated touch fields 232a and 232b serve the purpose
of arming the injector and initiating the start of
injection.

20 On the other hand, the "display screen" display
field 234 and associated touch fields 234a and 234b serve
the purpose of accessing any configuration (set-up)
information such as language (e.g., English, German,
French, Japanese, etc.) or KVO parameters or for reset
(e.g. zeroing) of the screen.

25 The "history" display field 236 may serve the
purpose of recalling past injection information that has
been stored, while the "help" field 238 may serve the
purpose of providing assistance to the operator in a
manner similar to the "help" arrangements found on a
typical computer or computer software system.

Finally, the "protocol" display field 239 and associated touch fields 240, 242 may serve the purposes of the identification, storage and recall of user-defined (saved) injection programs or (factory) pre-loaded programs.

5

Although the present invention, in accordance with at least one presently preferred embodiment, has been described hereinabove primarily in connection with an MR injector system, it is to be understood that other applications are possible without departing from the spirit and scope of the invention in general. For example, while it is known that CT, angiographic and ultrasound injectors to date have generally utilized only a single syringe, containing contrast medium, for administering solely contrast medium to a patient, the present invention broadly contemplates the use of two syringes in such environments - one for contrast medium and the other for flushing medium. Thus, it is contemplated that the present invention, in accordance with at least one presently preferred embodiment, could be utilized in such a context in that the operator could administer a protocol involving essentially any desired order of contrast medium and flushing medium phases.

10

15

20

A "pause" arrangement is also contemplated in accordance with at least one presently preferred embodiment of the present invention. A "pause" phase would essentially be similar to a "hold" phase in that it would represent a user-selected and programmed period of time in which no programmed injection of contrast medium or flushing medium is taking place. However, it would differ from a "hold" phase in the respect that it could essentially be a preprogrammed "hold" of limited duration

25

30

that ends with an automatic transition to the next
infusion phase (if any) in the protocol, whereas a "hold"
phase would be of indefinite duration, with the protocol
only to be reactivated by a manual prompt from the
operator. Although "pause" phases have been known in
conjunction with CT imaging arrangements, they are
apparently not known in conjunction with MR imaging
arrangements.

It should be appreciated that the inventive
arrangements described hereinabove afford a degree of
flexibility and versatility in programming an injection
protocol than apparently has been hitherto realized. One
distinct advantage inherent in such arrangements is their
adaptability to foreseeable changes in the injection arts
that may occur in the future, such as the development of
new contrast media or increases in the efficiency of
imaging scanners. For instance, it is conceivable that a
different type of contrast medium might necessitate its
injection into a patient via a much different protocol
than might now normally be used with existing contrast
media. Increases in imaging speed might also result in
the need for vastly different types of protocols than are
available on conventional equipment at present.

It will be appreciated that the flexibility and
versatility achieved in accordance with at least one
presently preferred embodiment of the present invention,
with the use of an automatic arrangement, far outstrips
any flexibility and versatility that might be gained
through certain uses of existing injection arrangements.
For example, although it is conceivable to employ two or
more "SPECTRIS" systems for the purpose of executing a
composite protocol, made up of separate protocols from

the different systems, that might reflect a higher degree of versatility (e.g., by enabling the execution of a second contrast medium phase after a flushing medium phase), it will be appreciated that such an arrangement would be cumbersome, difficult to manage, and possibly inaccurate, in that one or more operators would need to ensure that one phase on one system starts immediately after another phase on another system. Manual injection is, of course, also possible, even to such an extent that different injections, representing distinctly different contrast medium and flushing medium phases, could be executed one after the other by one or more medical personnel. Again, though, such an arrangement would appear to prone to the potential of great inaccuracy, not only in terms of the timing of the successive injections but also in terms of the flowrates being used and the difficulty in keeping them constant over the duration of each phase (if indeed constant flowrates are desired).

Several other advantages would appear to be attainable in accordance with at least one presently preferred embodiment of the present invention. For example, an entire protocol can be stored and recalled for future use. The injector can reserve the flushing medium that is needed for an entire protocol and can alert the operator, before an injection commences, as to insufficient fluid volume. Moreover, in a multi-phased protocol that includes flushing and has an intermediate "hold" phase, the protocol can shut off flow in a "KVO" state automatically in order to preserve any necessary flushing medium for a subsequent pre-programmed flushing phase.

Although a maximum of six phases for one protocol has been described hereabove, it will be appreciated that the present invention broadly contemplates that no maximum on the number of phases in a protocol necessarily need be imposed.

Although all types of phases, especially contrast medium and flushing medium phases, have essentially been described hereinabove as being linear in nature (i.e., having a fixed flowrate over the duration of the phase), it should be understood that the present invention also broadly contemplates the programming and execution of phases that are not linear in nature. For example, it is conceivable that a contrast medium or flushing medium phase (and possibly even a "KVO" phase) could represent a non-linear function, in which the flowrate could possibly be variable over the duration of the phase and could be programmed in by means of an equation, lookup table or other suitable arrangement. In the case of "KVO", it is even conceivable that short "bursts" of flushing medium could be emitted at a variable rate instead of a fixed rate.

Although syringes have been specifically contemplated hereinabove for use in injection protocols, as a means for storing and administering contrasting medium or flushing medium, it is to be understood that other arrangements for this purpose are conceivable within the scope of the present invention, such as, for example, the use of peristaltic pumps.

In the context of the present disclosure, the terms "infusion" and "injection", and their grammatical derivations, are to be construed as being interchangeable

and are meant to refer to essentially any of a wide range of arrangements for introducing fluid into a patient.

5 If not otherwise stated herein, it may be assumed that all components and/or processes described heretofore may, if appropriate, be considered to be interchangeable with similar components and/or processes disclosed elsewhere in the specification, unless an express indication is made to the contrary.

10 If not otherwise stated herein, any and all patents, patent publications, articles and other printed publications discussed or mentioned herein are hereby incorporated by reference as if set forth in their entirety herein.

15 It should be appreciated that the apparatus and method of the present invention may be configured and conducted as appropriate for any context at hand. The embodiments described above are to be considered in all respects only as illustrative and not restrictive. The scope of the invention is defined by the following claims rather than the foregoing description. All changes which come within the meaning and range of equivalency of the claims are to be embraced within their scope.